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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,014	06/27/2003	Robert Andrew Badley	ISA-002.01	8357
63767	7590	03/09/2007		
FOLEY HOAG, LLP PATENT GROUP, (w/ISA) 155 SEAPORT BLVD. BOSTON, MA 02210-2600			EXAMINER RAMILLANO, LORE JANET	
			ART UNIT	PAPER NUMBER
			1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/609,014

Applicant(s)

BADLEY ET AL.

Examiner

Lore Ramillano

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-19, 21, 23-36 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17-19, 21, 23-36 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In applicant's reply filed on 12/14/06, applicant amended claims 1-14, 17-19, 21, and 23-35; cancelled claims 15-16, 20, 22, and 37-40; and added new claims 41-44.

Response to Amendment

2. Examiner acknowledges applicant's confirmation of the election to prosecute claims 1-36.
3. The objection to the drawings has been withdrawn.
4. The objection to claims 8, 15, and 33 is withdrawn.
5. The rejection of claims 10, 15, 16, 18, and 20, under 35 U.S.C. 112, second paragraph, is withdrawn.
6. In light of applicant's amendments, the prior art rejections are withdrawn. New rejections follow.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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7. **Claims 1-3, 12, 13, 21, 23, 25, 27, 28, and 33-36**, are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. ("Anderson," US 6267722).

Anderson discloses a handheld assay reader comprising: a positioning member (i.e. Fig. 3, column 11, lines 45-49); at least one light source (i.e. Fig. 11, 1102 and 1104, i.e. UV light source), which produces at least one fluorescence excitation signal at an appropriate wavelength; and at least one viewing window, which comprises a nonreflective surface, for direct observation by a user that is located in the assay device (i.e. 314, Fig. 3, column 33, lines 21-28).

Anderson further discloses the following: the light source is contained in a housing, the housing further containing the assay device (column 36, lines 31-57); each wavelength of the at least one fluorescence excitation signal is different from each wavelength of the fluorescence from the least one luminescent label (column 23, line 65 to column 24, line 3); the first and second light sources can be exchanged between a first mode, and a second mode (i.e. column 38, lines 8-25); at least one fluorescence excitation signal comprises UV-light (i.e. column 20, lines 41-46); circuitry (i.e. column 22, lines 10-19); an LED indicator (i.e. column 22, lines 10-19); the assay reader and the assay device are non-separable or separable (i.e. Fig. 3 and Fig. 6); electro-chromic control indicator (i.e. column 21, line 57 to column 22, line 2); control indicator is a dye (i.e. column 21, line 57 to column 22, line 2); assay device is a lateral flow immunoassay device (i.e. column 3, lines 8-38); the assay device is a homogenous assay device (i.e. column 10, lines 29-34); and one or more assay devices, which

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comprise a capture zone and one or more luminescent labels (i.e. column 10, lines 29-44; column 11, line 65 to column 12, line 24).

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. **Claims 4-11, and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Hubscher et al. ("Hubscher," US 6824975).

Anderson does not specifically disclose a plurality of filters, and a wavelength of the at least one fluorescence excitation signal is greater or less than at least one wavelength of the fluorescence from the least one luminescent label.

Hubscher disclose a lateral flow assay device comprising a filter, different wavelengths of the emission signal, and fluorescent labels (column 6, lines 12-38).

Anderson and Hubscher are analogous art because they are from the same field of endeavor, an assay device for detecting the presence of human bodily fluids. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Anderson with the filter and wavelength limitations of Hubscher, as stated above, because it is well known in the art that fluorescent spheres, which are analytes attached to fluorescent microspheres or microparticles, are typically detected by a fluorescent reader that excites molecules at one particular wavelength (i.e. 526nm) and detects the emission of the fluorescent waves at another wavelength (i.e. 574nm). Additionally, it is known in the art to use an appropriate emission filter with a fluorescent reader. (Hubscher, column 6, lines 12-38).

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It would have been obvious to a person of ordinary skill in the art to modify Catt by including two different filters because when using two different fluorescent labels to react with analytes, it would be essential to have two different filters to detect for two different emission signals.

10. **Claims 17-19, 24, 26, and 29-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Catt et al. ("Catt," US 6235241).

Anderson does not specifically disclose a lens; a battery, and a batter indicator.

As to claims 17-19, Catt discloses an assay result reader, which comprises a columated source of electromagnetic radiation, using conventional focusing means, such as lenses (i.e. column 2, lines 27-30).

Anderson and Catt are analogous art because they are from the same field of endeavor, an assay device for detecting the presence of human bodily fluids. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Anderson with the lens limitation of Catt, as stated above, because it would be beneficial to include a focusing means, such as lens, to Anderson's device since it would ensure that the incident electromagnetic radiation is of substantially uniform intensity (i.e. column 2, lines 25-26).

As to claims 24, 26, and 29-32, Catt discloses a battery connected to the light source and circuitry (430, Fig. 4b, column 11, line 59 to column 12, line 1-36); and a control indicator or other indicators (i.e. electro-chromic, or fluorescent dye) on the outer surface of the reader (column 11, line 35 to column 12, line 15).

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At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Anderson with the battery, and a battery indicator limitations of Catt, as stated above, because it would be beneficial to include a source of energy, such as a battery, and a battery indicator, to ensure that the energy dependent components, such as an LED, functions at maximum capacity when the assay reader is being used.

11. **Claims 41-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson.

While Anderson does not specifically disclose having a label comprising a lanthanide metal ion, a microsphere, or a chelate, Anderson discloses having a label that may be any physical or chemical label capable of being detected on the solid support using a reader, preferably a reflectance reader, and capable of being used to distinguish the reagents to be detected from other compounds and materials in the assay. The labels include, but are not limited to enzyme-substrate combinations that produce color upon reaction, colored particles, such as latex particles, colloidal metal or metal or carbon sol labels, fluorescent labels, and liposome or polymer sacs, which are detected due to aggregation of the label. (i.e. column 11, line 11 to column 12, line 24).

It would have been obvious to a person of ordinary skill in the art to specifically utilize a label which comprises a lanthanide metal ion, a microsphere, or a chelate, because utilizing such labels are well known to those of skill in the art and it would be desirable to utilize a label which comprises a lanthanide metal ion, a microsphere, or a

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chelate because they are well known in the art to be suitable labels for fluorescence-based assays.

Response to Arguments

12. Applicant's arguments with respect to claim 1-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be


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reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano
Examiner
Art Unit 1743

3/3/07


Jill Warden
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